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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,155	01/16/2004	Douglas A. Hettrick	P-11316.00	9070

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER

JOHNSON, SHEVON ELIZABETH

ART UNIT PAPER NUMBER

3766

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/760,155

Applicant(s)

HETTRICK ET AL.

Examiner

Shevon E. Johnson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☒ Claim(s) 1 and 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 8/14/2006. Claims 1-43 are pending. Claims 5, 7, 17, 19 and 38 have been canceled.

Claim Objections

2. Claims 1 and 2 are objected to because of the following informalities: the claims are redundant. The Examiner suggest that in lines 5-8 of claim 1 should be deleted and replaced with "wherein enabling therapy comprising delivering therapy when hemodynamic compromise is present, and disabling therapy when hemodynamic compromise is not present."

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Response to Arguments

3. Applicant's remarks in regards to claims 1-31 and 36-42 have been fully considered but they are not deemed persuasive.

The 35 U.S.C. 102(b) rejections of claims 1-31 as being anticipated by Thong et al. (U.S. Patent 2002/0120300) have been withdrawn in light of pg. 1 of Applicant's remarks.

In the Office Action dated 5/16/06, claims 1-31 were rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. Patent No. 5,156,148), hereinafter Cohen.

The Applicant contends that Cohen fails to teach if atrial fibrillation is detected disabling therapy when hemodynamic compromise is not present.

However, Applicant also states that Cohen teaches "... not producing an output signal to a malfunction correction means when an atrial fibrillation malfunction is not detected" (pg. 2, lines 15-16 of Applicant's remarks).

The Examiner interprets "producing an output signal to a malfunction correction means when a stable or unstable atrial fibrillation malfunction is detected and not producing an output signal to a

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malfunction correction means when an atrial fibrillation malfunction is not detected to be synonymous with "enabling the therapy when hemodynamic compromise is present, and disabling therapy when hemodynamic compromise is not present".

Therefore, the 35 U.S.C. 102(b) rejections of claims 1-31 as being anticipated by Cohen are maintained. In addition, since claims 36-42 are traversed by Applicant based on the same argument put forth for claims 1-31 as being anticipated by Cohen, the rejections of claims 36-42 are also maintained. New claim 43 is also rejection under 35 U.S.C. 102(b) as being anticipated by Cohen (see below).

----- PRIOR OFFICE ACTION DATED 5/16/2006 (updated below) -----

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. Patent No. 5,156,148).

In regards to claim 1, Cohen discloses a method comprising: detecting a heart malfunction (col. 7, lines 5-6) such as atrial fibrillation (col. 7, lines 32-37); measuring hemodynamic performance (col. 6, lines 25-28); and inherently enables therapy (col. 5, lines 14-26) based on the measured hemodynamic performance (col. 6, line 62 – col. 7, line 4), further described in the references cited by Cohen (col. 7, line 67 - col. 8, line 11).

In regards to claim 2, Cohen discloses a method further comprising delivering the therapy when the therapy is enabled (col. 7, lines 5-37; col. 8, lines 1-11).

In regards to claim 3, Cohen discloses a method wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation (col. 7, lines 5-37).

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In regards to claims 4 and 17, Cohen discloses a method wherein the therapy is atrial defibrillation therapy (col. 7, lines 5-37).

In regards to claim 5, Cohen discloses a method wherein enabling therapy further comprises: determining whether hemodynamic compromise is present based on the hemodynamic performance during fibrillation; and enabling the therapy when hemodynamic compromise is present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 6, Cohen discloses a method comprising storing information about the hemodynamic compromise (col. 6, lines 38-51).

In regards to claim 7, Cohen discloses a method comprising withholding therapy when hemodynamic compromise is not present (col. 6, lines 52-61).

In regards to claim 8, Cohen discloses a method wherein determining whether hemodynamic compromise is present further comprises: measuring a hemodynamic performance baseline during normal sinus rhythm; comparing the hemodynamic performance during fibrillation to the hemodynamic performance baseline to determine whether a change in hemodynamic performance has occurred; and determining presence of hemodynamic compromise when the change exceeds a threshold (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 9, Cohen discloses a method wherein the hemodynamic performance baseline and the hemodynamic performance during fibrillation are measured using at least one hemodynamic performance parameter (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 10, Cohen discloses a method wherein the hemodynamic performance parameter includes at least one of electrogram (EGM), electrocardiogram (ECG), atrial pressure, ventricular pressure, arterial pressure, flow, pulmonary venous flow, acceleration, atrial dimension, ventricular dimension, thoracic impedance, intramyocardial impedance, velocity, QT interval, ST segment, blood oxygen content, myocardial oxygen consumption, change in right ventricular pressure versus time (dRVP/dt), and MVO₂/PO₂ (col. 7, lines 44-57).

In regards to claim 11, Cohen discloses a method wherein the hemodynamic performance baseline and the hemodynamic performance during fibrillation are each measured using a combination of at least two hemodynamic performance parameters (col. 6, lines 62-68; col. 7, lines 1-4, 44-57, 67-68; col. 8, lines 1-11).

In regards to claims 12-16, Cohen discloses the method substantially as claimed except wherein quantifying severity of or determining the presence of hemodynamic compromise when the change exceeds a threshold expressed as an absolute change (fixed), percentage change (varying), rate of change in hemodynamic performance (col. 7, line 67 - col. 8, line 11).

In regards to claim 18, Cohen discloses a system for controlling application of therapy to a heart, the system comprising: a first sensor 12 that detects atrial fibrillation (col. 6, lines 28-37); a second sensor 11 that measures hemodynamic performance during fibrillation (col. 6, lines 20-28); and a processor 13 that determines whether hemodynamic compromise is present based on the hemodynamic performance during atrial fibrillation, and enables delivery of therapy when hemodynamic compromise is present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 19, Cohen discloses a system wherein the therapy is withheld when hemodynamic compromise is not present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 20, Cohen discloses a system wherein the processor stores information about the hemodynamic compromise (col. 6, lines 38-51).

In regards to claim 21, Cohen discloses a system wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation (col. 7, lines 5-37).

In regards to claim 22, Cohen discloses a system wherein the therapy is atrial defibrillation therapy (col. 7, lines 5-37).

In regards to claim 23, Cohen discloses a system wherein the second sensor further measures hemodynamic performance during normal sinus rhythm (col. 6, lines 52-61).

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In regards to claim 24, Cohen discloses a system wherein the processor compares the hemodynamic performance during fibrillation to the hemodynamic performance during normal sinus rhythm to determine whether a change in hemodynamic performance has occurred, and to determine presence of hemodynamic compromise when the change exceeds a threshold (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 25, Cohen discloses a system wherein the hemodynamic performance during normal sinus rhythm and the hemodynamic performance during fibrillation are measured using at least one hemodynamic performance parameter (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 26, Cohen discloses a system wherein the hemodynamic performance parameter includes at least one of electrogram (EGM), electrocardiogram (ECG), atrial pressure, ventricular pressure, arterial pressure, flow, pulmonary venous flow, acceleration, atrial dimension, ventricular dimension, thoracic impedance, intramyocardial impedance, velocity, QT interval, ST segment, blood oxygen content, myocardial oxygen consumption, change in right ventricular pressure versus time ($dRVP/dt$), and MVO_2/PO_2 (col. 7, lines 44-57).

In regards to claim 27, Cohen discloses a system wherein the hemodynamic performance during normal sinus rhythm and the hemodynamic performance during fibrillation are measured using a combination of at least two hemodynamic performance parameters (col. 6, lines 62-68; col. 7, lines 1-4, 44-57, 67-68; col. 8, lines 1-11).

In regards to claim 28, Cohen discloses a system wherein the threshold represents a specified minimum change in the hemodynamic performance during fibrillation compared to the hemodynamic performance during normal sinus rhythm (col. 6, line 62 – col. 7, line 4).

In regards to claim 29, Cohen discloses a system wherein the processor quantifies severity of hemodynamic compromise based on the measured hemodynamic performance (col. 6, line 62 – col. 7, line 4).

In regards to claim 30, Cohen discloses a system further including a telemetry device for wireless transmission of a message when hemodynamic compromise is present (col. 8, line 51 - col. 9, line 10).

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In regards to claim 31, Cohen discloses a system further including a telemetry device for wireless transmission of a message upon delivery of therapy (col. 8, line 51 - col. 9, line 10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (U.S. Patent No. 5,156,148) in view of Thong et al. (U.S. Patent Pub. 2002/0120300), as cited by the examiner.

In regards to claim 36, Cohen discloses a method of treating atrial fibrillation substantially as claimed except programming a time period. However, Thong discloses a method wherein programming a time period to automatically deliver the therapy (pg. 1, [0001]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as taught by Cohen, by incorporating the time period as taught by Thong in order to regulate the delivery of therapy and prevent unnecessary pain.

In regards to claim 37, Cohen discloses wherein determining whether hemodynamic compromise is present includes detecting a specified minimum change in hemodynamic performance measured at the programmed time period compared to hemodynamic performance measured during normal sinus rhythm (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 38, Cohen discloses further comprising withholding therapy when hemodynamic compromise is not detected (col. 6, lines 52-61).

In regards to claim 39, Cohen discloses wherein the fibrillation is atrial fibrillation (col. 7, lines 18-37).

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In regards to claim 40, Cohen discloses wherein the therapy is atrial defibrillation therapy (col. 7, lines 18-37).

In regards to claim 39, Cohen discloses wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation.

In regards to claim 42, Cohen discloses a computer-readable medium (col. 6, lines 38-41) containing instructions for causing a processor to: detect fibrillation (col. 7, lines 29-37); measure hemodynamic performance during fibrillation (col. 6, lines 28-37); measure hemodynamic performance during normal sinus rhythm (col. 6, lines 52-61); compare the hemodynamic performance during fibrillation to the hemodynamic performance during normal sinus rhythm to determine whether a change in hemodynamic performance has occurred (col. 6, line 62 – col. 7, line 4); detecting presence of hemodynamic compromise when the change exceeds a threshold (col. 7, line 67 – col. 8, line 11); and enable delivery of therapy when hemodynamic compromise is present (col. 7, lines 5-37).

In regards to claim 43, Cohen discloses a method comprising: detecting atrial fibrillation; measuring hemodynamic performance during atrial fibrillation; and enabling therapy based on the measured hemodynamic performance; wherein enabling therapy comprises determining whether hemodynamic compromise is present based on the hemodynamic performance during fibrillation, enabling the therapy when hemodynamic compromise is present, and disabling therapy when hemodynamic compromise is not present (col. 6, lines 56-61 and col. 9, lines 31-36), and wherein determining whether hemodynamic compromise is present further comprises: measuring a hemodynamic performance baseline during normal sinus rhythm; comparing the hemodynamic performance during fibrillation to the hemodynamic performance baseline to determine whether a change in hemodynamic performance has occurred; and determining presence of hemodynamic compromise when the change exceeds a threshold for at least a predetermined minimum time period (col. 6, line 20 – col. 8, line 11).

Finality

8. Applicant's amendment (claim 43) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

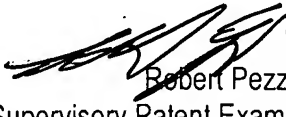
Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766


Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766